Supreme Court, U.S.
F I L E D
MAY 19 1995

No. 94-1527

IN THE
SUPREME COURT OF THE UNITED STATES
October Term, 1994

Barr Laboratories, Inc.,
Petitioner,

v.

Burroughs Wellcome Co.
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the court below correctly held, based on its *de novo* review of the record, including extensive offers of proof submitted by Petitioner, that Burroughs Wellcome Co. was entitled to judgment as a matter of law on its claim that United States Patents 4,724,232, 4,828,838, 4,833,130, 4,837,208 and 4,818,538 were infringed by Petitioner, were not invalid and named the correct inventors.

IDENTIFICATION OF CORPORATE AFFILIATES PURSUANT TO RULE 29.1

Pursuant to Supreme Court Rule 29.1, Respondent Burroughs Wellcome Co. states that it is a North Carolina corporation and a wholly owned subsidiary of The Wellcome Foundation Ltd., which in turn is a wholly owned subsidiary of Wellcome, p.l.c., which was recently acquired by Glaxo, p.l.c. and which has changed its name to Glaxo Wellcome, p.l.c. All of the subsidiaries of Burroughs Wellcome Co. are wholly owned.

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RESPONDENT'S BRIEF IN OPPOSITION

Respondent, Burroughs Wellcome Co. ("BW Co."), respectfully submits that a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit should not issue, because no question worthy of the exercise of the Court's certiorari jurisdiction is presented.

COUNTER-STATEMENT OF THE CASE

The Petition contains numerous misstatements and omissions with respect to the facts and law, thus necessitating this counter-statement. *See* Supreme Court Rule 15.1. Moreover, Respondent requests that the Court bear in mind that the alleged factual record presented to the District Court and the Federal Circuit by way of Petitioner's offer of proof was extremely one-sided and, Respondent contends, largely inaccurate. However, because this case was decided on a motion under *Fed. R. Civ. P.* 50(a), both lower courts were bound to accept the defendants' factual allegations as true and to draw all inferences in their favor. The Federal Circuit correctly held that the alleged facts upon which Petitioner relies were irrelevant to the issue of inventorship, and that judgment was appropriate as a matter of law based upon facts that are not in dispute.

The principal issue of this case is whether an independently corroborated, fully enabling, written description of the inventions claimed in the patents in dispute was sufficient to establish a legally cognizable conception, irrespective of whether, at the time of such written description, there was a "reasonable expectation" that the inventions would work. The five patents in dispute (the "BW Co. AZT patents") describe and claim pharmaceutical compositions and methods of treating people with Acquired Immune Deficiency Syndrome ("AIDS") and Human Immunodeficiency Virus ("HIV") disease using the drug, 3'-azido-3'-deoxythymidine ("AZT"). Petitioner argues that certain individuals employed by the NIH should have been

named as coinventors on the BW Co. AZT patents, because of the positive results of their blind, *in vitro* screening of AZT.[1] This screening was done at the request of BW Co. pursuant to a confidentiality agreement. A. 7973.[2]

Petitioner cannot dispute, however, that before the NIH employees conducted the blind screening of AZT or ever thought of AZT as a therapy for AIDS or HIV disease, BW Co. had prepared a fully enabling draft patent application describing the claimed inventions as they would thereafter be applied in practice. Pet. App. A, 14a. The draft patent application disclosed the routes of administration, dosage forms and dosing amounts and frequency that would later be approved by the Food and Drug Administration. A. 5321-25, A. 15077-80. As the Federal Circuit stated, Petitioner "concede[s that the draft patent application] would teach one skilled in the art to practice the inventions." Pet. App. A, 13a.

The BW Co. scientists' discovery of the use of AZT as a therapy for AIDS and HIV infection was the result of careful and painstaking research. They designed and implemented a test that allowed them to investigate a large number of candidate drugs. The test employed two different murine (mouse) viruses which, like HIV, were of a special

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[1] An *in vitro* test is one conducted in a laboratory system (e.g., a test tube) as opposed to an *in vivo* test which is performed in a living being. The term "blind screening" refers to the fact that when the NIH scientists screened AZT, it was identified only as "Compound S" -- they admittedly did not know the name or structure of the compound that they were screening.

[2] References to "Pet. App. __" are to the Appendix to the Petition for a Writ of Certiorari. References to "Pet. __" are to the Petition for a Writ of Certiorari. References to "A. __" are to the Record on Appeal.

type, known as a retrovirus. Petitioner does not dispute that the purpose of the murine tests was to identify potential antiviral agents for use in treating people with AIDS and HIV infection. A. 1606, 1655, 1684; A. 789, 792-93; A. 15245-49.

The BW Co. scientists did not select compounds for testing arbitrarily. They focused upon a category of compounds known as "nucleoside analogs." A. 795-96; A. 1618, 1920. Nucleoside analogs are analogs of the building blocks of DNA, and BW Co. had a long history of research with nucleoside analogs for use in treating viral infections, cancer and other diseases.[3] AZT, which is an analog of thymidine, was among the thousands of nucleoside analogs known in 1984. A. 796.

During the Summer and Fall of 1984, BW Co. tested more than one hundred compounds in its murine retrovirus screens. Most of these compounds were nucleoside analogs. A. 1684, 1820, 1823, 1920-21; A. 795-96. AZT was by far the most active compound tested. It was 1,000 times more potent than any antiretroviral compound ever tested at BW Co. and showed no toxicity to the cells used in the culture. A.1695; A. 2623.

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[3] Dr. Broder and his colleagues at the NIH did not focus their attention on nucleos[illegible] analogs until after BW Co. revealed to them that Compound S was [illegible]T. Before his involvement with BW Co., Dr. Broder was directing his attention to a very different type of compound, suramin. Although suramin demonstrated activity against HIV in test tube tests performed in Dr. Broder's laboratory, it turned out to be ineffective as an AIDS therapy, and in fact was extremely toxic. During his seminar at BW Co. in October 1984 (*see* Pet. 5), Dr. Broder tried to get BW Co. involved in his suramin research, but BW Co. was not interested. A. 918.

BW Co. submits that its research leading to the draft patent application is further evidence of its conception of compositions and methods of use of AZT for the treatment of AIDS and HIV disease before any involvement of the NIH. Petitioner does not dispute that BW Co. conducted the above-described research. Instead, Petitioner argues that one could not predict that a drug would be a successful AIDS therapy in humans based exclusively on the results of the murine retrovirus screens.[4] While BW Co. believes that its scientists did have a reasonable basis for believing that they had discovered a useful AIDS therapy, the District Court and the Federal Circuit correctly ruled that whether or not such a basis existed is irrelevant to the question of inventorship. Pet. App. A, 15a-16a.

The Federal Circuit held that conception, the completion of the mental part of invention, is the touchstone of invention. Pet. App. A, 8a. Conception has long been defined as "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Id.*, citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

Holding that the "conception analysis necessarily turns on the inventor's ability to describe his invention with particularity" (Pet. App. A, 9a), the Federal Circuit concluded

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[4] A drug intended for human use must, in addition to having activity against the disease-causing agent, also possess low toxicity and acceptable pharmacological and pharmacokinetic properties. As a result of BW Co.'s previous investigation of AZT as a possible antibacterial agent, the BW Co. scientists were aware of AZT's low toxicity and other advantageous characteristics. A. 15271-76; A. 937-38.

that the BW Co. draft patent application specifically set out the inventions, including an enabling disclosure, which was sufficient in this case

> to confirm that the inventors had concluded the mental part of the inventive process -- that they had arrived at the final, definite idea of their inventions, leaving only the task of reduction to practice to bring the inventions to fruition.

Pet. App. A, 15a.

The court specifically rejected Petitioner's arguments that a reasonable expectation of success that the invention will work is a necessary component of the inventor's definite and permanent idea. Pet. App. A, 9a-10a. The court also rejected the Petitioner's arguments that, in uncertain or experimental disciplines, some experimental confirmation is required before an inventor can have a complete conception. *Id.* Relying on long-standing precedent, the Federal Circuit held that an inventor need not know that the invention will work for conception to be complete, and that the inventor's reasons for choosing a particular approach are irrelevant to conception. *Id.*

For these reasons, the District Court held and the Federal Circuit affirmed that the extent to which the BW Co. murine test results were predictive of the utility of AZT as a therapy for AIDS or HIV disease was irrelevant to the issue of conception and therefore was irrelevant to Petitioner's allegations that the inventorship on the BW Co. AZT patents was incorrect. Both courts were also unpersuaded that Petitioner's allegations concerning the *in vitro* tests performed

at Duke University and at the FDA had any bearing on whether or not the NIH employees were coinventors.[5]

REASONS FOR DENYING THE WRIT

A. Summary of the Argument

Petitioner asks this Court to adopt its poorly defined and illogical "reasonable expectation" test for conception and, in so doing, to overturn more than one hundred years of precedent. This extraordinary request is based on dire and unfounded predictions of the impact of the Federal Circuit's decision and on the suggestion that different standards for conception should apply in uncertain fields of chemistry and biology than in other fields.

In defense of its novel theory, Petitioner confuses concepts of obviousness and utility -- which are requirements for patentability -- with conception, which is the seminal step in the inventive process. Petitioner incorrectly attempts to frame the issue as a choice between a "loose and a rigorous standard of conception." Pet. 18.

The writ should be denied. *First*, the Federal Circuit's decision is consistent with long-standing precedent. There is no conflict among the circuits on this standard, between the Federal Circuit's decision in this case and its decisions in other cases raising inventorship issues or between the rulings in this case and any ruling of this Court. Plenary review by this Court is therefore not warranted. *Second*, Petitioner's speculation that the decision will have a chilling effect on

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[5] Petitioner's unsupported allegations to this Court concerning its license under alleged "inchoate" rights of the NIH in the BW Co. AZT patents, the BW Co. pricing of AZT and Petitioner's alleged pricing plans should it ultimately prevail are completely irrelevant to the issue of inventorship.

research because companies can now simply make "lists" of compounds and thus obtain patent protection is illogical and lacks any historical basis. Federal Circuit precedent requires that an inventor must have conceived of an invention in sufficient detail to enable a person of ordinary skill to practice it. Thus, a complete conception for a pharmaceutical invention may require an inventor to describe such things as effective dosages, routes of administration, how to make the compound and the like. *Third*, if Petitioner's novel theory of conception were adopted, it would create confusion and uncertainty in both inventorship and priority determinations, upsetting decades of patent practice. No court has ever urged such a radical result -- and with good reason. *Fourth*, the issue is not whether a "loose" or "rigorous" standard is applied -- the existing standard of conception, as correctly defined by the Federal Circuit, is precise, demanding and yields predictable results.

B. Petitioner's "Reasonable Expectation" Theory is Contrary to Long-Standing Precedent.

The District Court held that an idea is definite and permanent when an inventor can adequately describe and preserve the idea. Pet. App. B, 31a. The Federal Circuit agreed, holding that "[t]he conception analysis necessarily turns on the inventor's ability to describe his invention with particularity." Pet. App. A, 9a. These holdings are consistent with more than one hundred years of precedent. The case of *Mergenthaler v. Scudder*, 11 App. D.C. 264, 1897 C.D. 724 (D.C. Cir. 1897), which articulated the "definite and permanent" language, relied on *Cameron & Everett v. Brick*, 1871 C.D. 89 (Comm'r Pat. 1871), which held that conception is complete "when [the invention] has assumed such shape in the mind that it can be described and illustrated . . . and when this is evidenced by such description

or illustration as to demonstrate its completeness." 1871 C.D. at 90. The Court of Customs and Patent Appeals, a predecessor of the Federal Circuit, has consistently held that conception turns on the ability of the inventor to describe the invention with sufficient particularity.

> It is sufficient [for conception] if an inventor is able to make a disclosure which would enable a person of ordinary skill in the art to practice the disclosure without extensive research or experimentation.

Applegate v. Scherer, 332 F.2d 571, 572, 141 U.S.P.Q. 796, 798 (C.C.P.A. 1964). The Federal Circuit recently confirmed this principle in *Fiers v. Revel*, 984 F.2d 1164, 1169, 25 U.S.P.Q. 2d 1601, 1605 (Fed. Cir. 1993) ("While one does not need to have carried out one s invention before filing a patent application one does need to be able to describe that invention with particularity.")

This precedent does not distinguish inventions on the basis of the predictability of the technical field within which they reside and, in fact, both of the above-cited cases involved inventions in highly unpredictable fields. The *Applegate* case involved an invention directed to compounds to be added to the Great Lakes for controlling sea lampreys. The *Fiers* case related to the cloning of a human interferon gene in bacteria, using genetic engineering techniques. The key is the ability of the inventor to place the complete invention in the hands of the public via a disclosure that would enable a person of ordinary skill to reduce it to practice. When, as in the present case, that standard is met, it is irrelevant whether the invention is in a predictable or unpredictable field.

Petitioner seeks to find support for its "reasonable expectation" theory from so-called "simultaneous conception and reduction to practice" cases.[6] Pet. 17. In such cases, the invention is the result of trial-and-error research, and the inventor cannot describe how to put the invention into practice until a successful experiment has been performed. *Alpert v. Slatin*, 305 F.2d 891, 894, 134 U.S.P.Q. 296, 299 (C.C.P.A. 1962). The Federal Circuit correctly found these cases to be inapposite, concluding that conception fails not merely because the field is unpredictable, but because prior to the successful experiment, the conception is incomplete, *i.e.*, the inventor cannot yet describe with sufficient specificity how to practice the invention. Pet. App. A, 11a.

Petitioner suggests that the Federal Circuit's opinion is internally inconsistent and "leaves the scientific community without a clear standard as to what constitutes conception in the fields of chemistry and biology." Pet. 11-12. This argument is based on the following language from the Federal Circuit's opinion:

> A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the *complete invention as it will be used in practice*.

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[6] The simultaneous conception and reduction to practice doctrine is an evidentiary tool for determining priority of invention, *i.e.*, determining who was the first to arrive at a complete conception. It is inapplicable to the present case, inasmuch as this is an originality and derivation case, not a priority dispute between independent inventors. *See MacMillan v. Moffett*, 432 F.2d 1237, 1240, 167 U.S.P.Q. 550, 553 (C.C.P.A. 1970) (The doctrine of simultaneous conception and reduction to practice does not apply in cases where the issue is originality or derivation.)

Pet. App. A, 11a-12a. (Emphasis added.)[7] Petitioner's characterization of this portion of the Federal Circuit's opinion as "confusing" and internally inconsistent stems from its reading the language out of context. The quoted language appears in the Federal Circuit's discussion of the simultaneous conception and reduction to practice cases. It does not, as Petitioner suggests, mean that a specific and fully enabling conception of an invention ceases to be a conception when there is a subsequent experimental failure. The point is simply that, in trial-and-error research, conceiving of a general goal does not amount to conception when the course of experimentation has not yet revealed to the inventor how the invention will be put into practice. In such a situation, the conception is not yet complete, because the inventor cannot make a disclosure of the invention that would enable its reduction to practice by one of ordinary skill. It is well established that,

> conception has been achieved when 'the inventive idea is crystallized in all of its essential attributes and becomes so clearly defined in the mind of the inventor as to be capable of being converted to reality and reduced to practice by the inventor or by ones skilled in the art.' *Technitrol, Inc. v. United States*, 440 F.2d 1362, 1369-70, 194 Ct.Cl. 596, 609 (1971).

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[7] The Novopharm defendants petitioned the Federal Circuit for rehearing, arguing that this statement in the Court's opinion represented its controlling definition of the law of conception, and that, in view of the alleged "experimental failures" of other entities to whom AZT (denominated as "Compound S") had been sent by BW Co. (Duke University and the U.S. Food and Drug Administration ("FDA")), the District Court's judgment should have been reversed. The Federal Circuit rejected Novopharm's petition without comment. Novopharm has filed a petition for writ of certiorari with this Court based on the same argument.

Amax Fly Ash Corp. v. United States, 514 F.2d 1041, 1047, 182 U.S.P.Q. 210, 215 (Ct. Cl. 1975).

In the present case, there is no dispute that before the NIH even began its blind screening of AZT, the BW Co. scientists had conceived of the use of AZT for treating AIDS and HIV disease in sufficient detail to enable them to describe to a skilled physician how to put the invention into practice.[8] Pet. App. A, 13a-14a. This is all that is required for conception. Since the conception was complete before Drs. Broder and Mitsuya had any involvement with AZT, they cannot be coinventors.

Petitioner is not the first to argue that an inventor must know or have a basis for believing that an invention will work before a conception is complete. The Federal Circuit's predecessor court, the C.C.P.A. has consistently rejected this argument over the past thirty years. In *Applegate v. Scherer*, the C.C.P.A. explicitly rejected the very argument that Petitioner makes here:

> Appellants seem to propose that there cannot be a conception of an invention of the type here involved in the absence of knowledge that the invention will work.

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[8] Petitioner contends that the testing of compounds against HIV in Dr. Broder's ATH8 cell line required special expertise. Pet. 6. Whether or not Dr. Broder's test required special expertise is irrelevant to the completeness of the conception by the BW Co. scientists before the NIH test was commenced. The inventions of the BW Co. AZT patents are directed to the treatment of patients, not the confirmation of activity in a test tube. Regardless of the skill required to perform the test tube procedure, it is not disputed that the BW Co. draft patent application contained sufficient detail to enable a skilled physician to treat a patient with AIDS or HIV disease. Therefore, the conception of the invention *as claimed* was complete before any NIH involvement.

> Such knowledge, necessarily, can rest only on an actual reduction to practice. To adopt this proposition would mean, as a practical matter, that one could never communicate an invention thought by him to another who is to try it out, for, when the tester succeeds, the one who does no more than exercise ordinary skill would be rewarded and the innovator would not be. *Such cannot be the law.*

332 F.2d at 573-74, 141 U.S.P.Q. at 799. (Emphasis added.) Similarly, in *MacMillan v. Moffett*, the C.C.P.A. held that Moffett's reasons or lack of reasons for including a compound in a group to be sent to MacMillan for antiperspirant screening were not relevant to the question of conception. 432 F.2d at 1239, 167 U.S.P.Q. at 552. *Also see, Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 U.S.P.Q. 453, 457-58 (C.C.P.A. 1974) (Conception of an anti-depressant drug held to be complete, notwithstanding the need for extensive animal and human testing, because nothing beyond the exercise of routine skill would have been required to demonstrate the utility of the drug.)

Indeed, an inventor need not even understand the scientific basis for the invention in order to obtain a patent. *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435-36 (1911) ("It is certainly not necessary that he understand or be able to state the scientific principles underlying his invention, *it is immaterial whether he can stand a successful examination as to the speculative ideas involved.*" (Emphasis in original; citations omitted.)

The adoption of Petitioner's "reasonable expectation" theory of conception would require that long-standing precedent and well-established patent practice be overturned.

Petitioner has fallen far short of justifying such extraordinary action.

Petitioner has also failed to point to any conflict among the circuits, conflict with prior Federal Circuit rulings or conflict between the ruling in this case and any ruling of this Court warranting plenary consideration by this Court.

C. Petitioner's Speculations About Dire Consequences of the Federal Circuit's Decision are Meritless

Petitioner speculates here, as it did before the Federal Circuit, that, unless its "reasonable expectation" theory of conception is adopted, there will be a chilling effect on research. Petitioner contends that the Federal Circuit's decision will allow companies to preempt fields by making long lists of known compounds for testing for a particular utility and to claim that such lists constitute conception of the use of each of the listed compounds. Petitioner's predictions are baseless, and reflect a lack of understanding of the patent system.

First, as is clear from the precedent discussed in the preceding section, a conception cannot be established merely by including a compound on a list. The inventor must have conceived the invention in sufficient detail to enable a person of ordinary skill to reduce it to practice. This conception must be independently corroborated. Pet. App. A, 9a. *Also see Price v. Symsek*, 988 F.2d 1187, 1194-95; 26 U.S.P.Q.2d 1031, 1036-37 (Fed. Cir. 1993). In the pharmaceutical field, a complete conception often requires that the inventor be able to describe the structure of the drug and how to make it along with such details as effective dosages, routes of administration, dosage forms, frequency of dosing and the like.

Moreover, even the establishment of a complete conception does not guarantee the conceiver a patent. The requirements for patentability, including novelty, nonobviousness and utility must be met. 35 U.S.C. §§ 101, 102 and 103. In addition, the rights of one who conceives, but subsequently abandons, suppresses or conceals an invention, will be subordinate to those of a later inventor who perfects and patents the invention. Indeed, one who conceives but does not exercise diligence in reducing the invention to practice will forfeit the patent rights to a later conceiver who is the first to reduce to practice. 35 U.S.C. § 102(g).

Thus, contrary to Petitioner's predictions, one cannot preempt a field simply by making a list. The conception must be sufficiently detailed to enable the reduction of the invention to practice. The conceiver must then act diligently in reducing the invention to practice, and must take steps to place the invention in the hands of the public. Finally, the inventor must establish to the satisfaction of the Patent and Trademark office that the invention is new, useful and nonobvious. Only after meeting all of these standards, will the inventor be rewarded with a patent.

Moreover, the Federal Circuit's decision merely applied the law as it has existed for over one hundred years. The dire consequences predicted by Petitioner simply have not occurred over that time period and, as discussed above, there is no reason that they will occur in the future.

D. Petitioner's "Reasonable Expectation" Theory of Conception Would Lead to Confusion and Would Discourage Cooperative Research

Petitioner's novel proposed test for conception would unnecessarily complicate both priority and inventorship determinations. In patent interferences, priority of inventorship often turns on the question of who was first to conceive. *See, Fiers v. Revel.* In general, priority is awarded to the party who first conceives and reduces the invention to practice. 35 U.S.C. § 102(g). The filing of a patent application which meets the requirements of 35 U.S.C. § 112 has long been recognized as a constructive reduction to practice. Accordingly, the filing date of an enabling patent application conclusively establishes the latest date on which an invention was made. Chisum, *Patents*, Vol. 3, § 10.03[1] at 10-27 (1994). In interference practice, the party with the earliest filing date is designated the "senior party." In general, the senior party will be awarded the patent unless another party can prove a date of invention prior to the senior party's filing date. Collins, *Current Patent Interference Practice*, § 4.8 at 86.1 (1992).

Petitioner's proposed "reasonable expectation" test for conception would substantially change this long-standing approach to the resolution of patent interferences. Under Petitioner's theory, the filing of an enabling patent application would not establish a date of invention unless the applicant could also show that there was a reasonable basis for believing that the invention would work. As the present case demonstrates, it could be expected that in every patent interference in which the junior party could not establish a date of invention prior to the senior party's filing date, the junior party would challenge the "reasonableness" of the senior party's belief that the invention would work. Patent

applications claiming pharmaceutical inventions are often filed before testing in humans or animals has been done; therefore, it could be anticipated that a substantial proportion of such patent applications would be challenged on the basis of the sufficiency of the applicant's data in supporting a reasonable belief that the invention will work.[9]

The uncertainty and confusion created by Petitioner's conception theory would not be limited to patent interference proceedings. Virtually every issued patent in the fields of chemistry, biotechnology and pharmaceuticals would be subject to challenge on the grounds of improper inventorship or invalidity based on prior art or prior invention of another.

Petitioner argues that unless its "reasonable expectation" theory is adopted, the role of the NIH in pharmaceutical research will be adversely affected. Pet. 15. Petitioner's argument is backwards. The NIH has encouraged companies to submit compounds for testing in programs such as the

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[9] It is unclear that the results of Dr. Broder's *in vitro* test would meet Petitioner's "reasonable expectation" standard. *See In re Balzarini*, 1991 Pat. App. LEXIS 37 (Bd. Pat. App. & Int. 1991) (Claim to a method for treating AIDS rejected where only proof of utility was positive activity against the HIV virus in *in vitro* tests similar to those tests used in Dr. Broder's laboratory.) Moreover, Petitioner's test is confusing. During oral argument before the Federal Circuit, Petitioner's counsel was asked whether the "reasonable expectation" test would preclude a genius from establishing a conception based upon insight that might not be considered reasonable by others. Petitioner's counsel responded that a genius would have the reasonable basis for believing that the invention would work. Thus, Petitioner's test is subjective, and the same idea might constitute a conception for one person and not for another. The Patent Office and the courts would have to look into the mind of the putative inventor and perhaps administer an I.Q. test to ascertain whether that person had a reasonable basis for believing that the invention would work.

National Cancer Institute cancer screens. The agency has consistently assured the private sector that patent rights will not be jeopardized by the submission of compounds for testing. For example, the following statement appears in a National Cancer Institute publication, a transcript of the proceedings of the Committee for the Establishment of the Anti-AIDS Screening Program at the National Cancer Institute, Division of Cancer Treatment:

> All this is made possible because of the confidentiality agreement, which we execute with the suppliers. It makes it possible to treat each one of the competing companies in an individual fashion. The key point is when you supply us any compound, you are considered the inventor for all patent purposes.
>
> The conceptional idea starts at the point you donate the compound for screening. (As I said, 98 percent of the compounds we acquire are voluntary contributions from the outside community.) The lead optimization process then is also coupled with this initial fact. So whatever variations we do are simply variants of the initial idea. Again, we do that very carefully by working with the suppliers of the compounds. We do that absolutely ensuring that the patent rights revert back to the original supplier.

Trial Exhibit 1428.

Under Petitioner's theory, patent rights would be severely jeopardized if an inventor were to send a compound to another for testing, and the testing confirmed the activity. The adoption of Petitioner's novel theory of conception would have a chilling effect on cooperative research

activities, particularly those involving government laboratories.

E. The Existing Law Imposes a Precise and Rigorous Standard for Conception and Need Not be Changed

Petitioner argues that the issue is one involving a choice between a "loose" and a "rigorous" standard for conception. In defense of its argument, Petitioner confuses issues of obviousness and utility -- both standards for patentability -- with conception. Conception is the seminal act in the process of invention. The fact that one conceives an invention does not assure one of obtaining a patent. But if a patent does issue, the patent law has traditionally recognized that the person who performed the mental act of conception is the inventor.

Petitioner is correct that the patent statute and applicable Supreme Court precedent establish high standards for patentability. To obtain a patent, the invention must have a practical utility and must not have been obvious over the prior art. However, here there is no question that the inventions claimed in the BW Co. AZT patents meet both the utility and nonobviousness requirements. Petitioner's selective quotations from this Court's opinions in *Brenner v. Manson*, 383 U.S. 519 (1966), and *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950), are inapposite to the issue of this case. As reflected in the BW Co. draft patent application, the BW Co. scientists conceived of a practical utility of their inventions (the treatment of AIDS and HIV disease), and thus met the standards set forth in *Brenner v. Manson*.

Petitioner unwisely attacks the patent system (Pet. 14-15), when, as a generic drug company, its only source of new

products is the research-oriented pharmaceutical industry. The incentives of the patent system are essential to encouraging investments in the expensive, high-risk research required to bring about new pharmaceutical products.

As discussed above in Section B, the time-honored test for conception which was applied in this case by the District Court and the Federal Circuit cannot seriously be criticized as "loose." To establish a complete conception, an inventor must show, by independently corroborated evidence, possession of all of the details of a complete and operative invention as it will thereafter be applied in practice. The mental conception must be developed to the point that all that is required for its reduction to practice is the exercise of ordinary skill. This standard is rigorous, and undisputed evidence in this case establishes that the BW Co. scientists met that standard before any involvement of the NIH employees.

CONCLUSION

For the foregoing reasons, this case does not warrant plenary review and the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

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